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Human Cloning

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Judith A. Johnson
Specialist in Life Sciences
Domestic Social Policy Division

Erin D. Williams
Specialist in Bioethical Policy
Domestic Social Policy Division

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Human Cloning

Summary

In December 2005, an investigation by Seoul National University, South Korea, found that scientist Hwang Woo Suk had fabricated results on deriving patient-matched stem cells from cloned embryos — a major setback for the field. In May 2005 Hwang had announced a significant advance in creating human embryos using cloning methods and in isolating human stem cells from cloned embryos. These developments have contributed to the debate in the 109th Congress on the moral and ethical implications of human cloning. Scientists in other labs, including Harvard University and the University of California at San Francisco, intend to produce cloned human embryos in order to derive stem cells for medical research on diabetes, Parkinson's disease, and other diseases.

President Bush announced in August 2001 that for the first time federal funds would be used to support research on human embryonic stem cells, but funding would be limited to “existing stem cell lines.” Federal funds can not be used for the cloning of human embryos for any purpose, including stem cell research. In July 2002 the President's Council on Bioethics released its report on human cloning which unanimously recommended a ban on reproductive cloning and, by a vote of 10 to 7, a four-year moratorium on cloning for medical research purposes. The ethical issues surrounding reproductive cloning (commodification, safety, identity), and therapeutic cloning (embryos' moral status, relief of suffering), impact various proposals for regulation, restrictions, bans, and uses of federal funding. In January 2002, the National Academies released *Scientific and Medical Aspects of Human Reproductive Cloning*. It recommended that the U.S. ban human reproductive cloning aimed at creating a child. It suggested the ban be enforceable and carry substantial penalties. The panel noted that the ban should be reconsidered within five years. However, the panel concluded that cloning to produce stem cells should be permitted because of the potential for developing new therapies and advancing biomedical knowledge.

On May 24, 2005, the House passed H.R. 810 (Castle), which would allow federal support of research that uses human embryonic stem cells regardless of the date on which the stem cells were derived from a human embryo, thus negating the Bush stem cell policy limitation on “existing stem cell lines.” In July of 2006, the Senate passed H.R. 810 and President Bush vetoed it, the first veto of his presidency. An attempt in the House to override the veto was unsuccessful. Action on the Weldon bill (which passed the House in the 108th Congress and stalled in the Senate) is also possible; it was reintroduced in the 109th Congress as H.R. 1357 and S. 658 (Brownback). The bill bans the process of cloning as well as the importation of any product derived from an embryo created via cloning. It bans not only reproductive applications, but also research on therapeutic uses, which has implications for stem cell research. Advocates of the legislative ban say that allowing any form of human cloning research to proceed raises serious ethical issues and will inevitably lead to the birth of a baby that is a human clone. Critics of the ban argue that the measure would curtail medical research and prevent Americans from receiving life-saving treatments created overseas. This report will be updated as needed.

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Human Cloning

Background

The term “cloning” is used by scientists to describe many different processes that involve making copies of biological material, such as a gene, a cell, a plant or an animal. The cloning of genes, for example, has led to new treatments developed by the biotechnology industry for diseases such as diabetes and hemophilia. In the context of this report, a human embryo produced via cloning involves the process called somatic cell¹ nuclear transfer (SCNT). In SCNT, the nucleus of an egg is removed and replaced by the nucleus from a mature body cell, such as a skin cell. In cloning, the embryo is created without sexual reproduction: there is no joining of egg and sperm.

Concern over the possibility of producing a human clone increased with the announcement on February 24, 1997, that scientists in Scotland had used SCNT in 1996 to produce the first cloned adult mammal, Dolly, the sheep. Ian Wilmut’s group at the Roslin Institute in Edinburgh removed the nucleus from a sheep egg and replaced it with the nucleus of a mammary gland cell from an adult sheep. The resulting embryo was then transferred to the uterus of a surrogate sheep. A total of 277 such embryos were transferred, but only one lamb was born.² Analyses of Dolly’s genetic material confirmed that she was derived from the sheep mammary cell. Dolly was euthanized on February 14, 2003, after developing a lung infection. Although some claim that her somewhat early death at six years was related to being a clone, scientists at the Roslin Institute believe her ailment may be due to the fact that she was raised indoors (for security reasons) rather than as a pastured sheep, which can live to 11 or 12 years of age.³

Although scientists have been successful in using SCNT to produce other animals (such as a cat, goat, cow, horse, mule, pig, mouse, and rabbit), the efficiency of the procedure is still very low and frequently results in abnormal development. Proponents maintain that one day cloning may be very useful for a number of agriculture applications, including the improvement of livestock. Currently, cloned mice are used for basic research on human health applications.

Cloning Attempts in South Korea. Charges of ethical and scientific misconduct have clouded the reputation of scientists involved in deriving stem cells

¹ A somatic cell is a body cell, as opposed to a germ cell, which is an egg or sperm cell.

² I. Wilmut et al., “Viable Offspring Derived from Fetal and Adult Mammalian Cells.” *Nature*, vol. 385, Feb. 27, 1997, pp. 810-813.

³ G. Kolata, “First Mammal Clone Dies; Dolly Made Science History,” *New York Times*, Feb. 15, 2003, p. A4.

from cloned human embryos. In February 2004 scientists at the Seoul National University (SNU) in South Korea announced the first isolation of stem cells from a cloned human embryo. In May 2005 this same group announced they had achieved major advances in the efficiency of creating human cloned embryos using SCNT and in isolating human stem cells from the cloned embryos. These eleven new stem cell lines were derived using cells from patients with either spinal cord injury, diabetes, or an immune deficiency and offered the hope of one day providing treatments with patient-matched cells.⁴ The team attributed the improved success rate in part to the use of freshly harvested eggs from younger fertile women instead of leftover eggs from older women who received fertility treatments.⁵

However, serious concerns about the achievements of the SNU group began in November 2005 when a co-author of the 2005 paper, Gerald Schatten of the University of Pittsburgh, accused Woo Suk Hwang, the lead researcher of the SNU group, of ethical misconduct.⁶ In violation of some ethical standards and contrary to statements made in the 2005 paper, junior scientists in the SNU lab secretly donated their own eggs for the experiments and they along with other women received payment for their role. The accusation halted plans for a collaboration between the SNU scientists and US and UK labs that had been announced only one month earlier and resulted in Hwang resigning from all public positions on November 24, 2005.

On December 12, 2005, Schatten asked that his name be removed from the 2005 paper when he learned that the work may have been fabricated.⁷ In early December, scientists in South Korea began questioning the validity of photographs and other scientific evidence presented in the 2005 paper and called for an independent analysis of the data. The University of Pittsburgh and SNU began separate investigations into the charges. On December 15, 2005, another co-author of the 2005 paper, Sung Il Roh, stated to the Korean media that the research had been fabricated and that the 2005 paper should be retracted. Hwang agreed to the retraction on December 16, but continued to defend the scientific results.⁸

A preliminary report released on December 23, 2005, by SNU stated that nine of the eleven stem cell lines described in the 2005 paper were deliberately fabricated

⁴ Gretchen Vogel, "Korean Team Speeds Up Creation of Cloned Human Stem Cells," *Science*, vol. 308, May 20, 2005, pp. 1096-1097.

⁵ In both cases, women receive a series of hormone injections that stimulate the ovaries to produce multiple eggs which are removed via a surgical procedure. There is a small chance (up to 5%) that a woman will over respond to the hormone injections resulting in complications; in rare situations the outcome is fatal. The long-term consequences of the hormone injections are unknown.

⁶ Gretchen Vogel, "Collaborators Split over Ethics Allegations" *Science*, Nov. 18, 2005, p. 1100.

⁷ The Associated Press, "South Korean's Cloning Research Challenged," *The New York Times*, Dec. 13, 2005.

⁸ Gordan Fairclough, "South Korean Scientist Denies Falsifying Stem-Cell Research," *The Wall Street Journal*, Dec. 17, 2005, p. A4.

and the remaining two stem cell lines were still under investigation.⁹ On December 29, 2005, Seoul National University stated that the remaining stem cell lines were not patient-matched and were not derived through cloning.¹⁰ On January 10, 2006, SNU stated that results of the 2004 paper, which reported the first derivation of stem cells from a cloned human embryo, were also a deliberate fabrication.¹¹

Cloning Attempts in the United Kingdom and United States.

Scientists in the United Kingdom, at the University of Newcastle and the University of Edinburgh, and scientists in the United States, at Harvard University, Advanced Cell Technology and the University of California in San Francisco, are working on deriving patient-matched stem cells from cloned human embryos.¹²

In the United Kingdom, scientists performing human cloning and embryonic stem cell research are regulated by the Human Fertilization and Embryology Authority (HFEA). A team of scientists headed by Alison Murdoch at the University of Newcastle received permission from HFEA to start therapeutic cloning experiments in August 2004.¹³ In May 2005, the team announced that it had created a cloned human embryo but has not yet reported success in isolating stem cells from a cloned human embryo. A research team headed by Ian Wilmut at the University of Edinburgh also is seeking permission from HFEA to begin working on SCNT experiments using human embryos.

Scientists at the Harvard Stem Cell Institute intend to produce cloned human embryos for research studies on juvenile diabetes, Parkinson's disease, and several other diseases.¹⁴ In November 2003, the research group, headed by Douglas Melton and Kevin Eggan, submitted their proposal to a Harvard committee composed of ethicists, scientists and public policy experts. Preliminary permission to proceed with the research was granted in January 2005, provided that a number of specific restrictions were followed and approval was received from a second committee charged with safeguarding the use of human subjects in research.¹⁵ The restrictions include limitations on the developmental age of the cloned embryos used in experiments, a prohibition on reproductive cloning, and a limitation on paying only

⁹ Rick Weiss, "Korean Stem Cell Lines Faked," *The Washington Post*, December 23, 2005, p. A1.

¹⁰ Choe San-Hun, "Panel further discredits Stem Cell Work of South Korean Scientist," *The New York Times*, Dec. 29, 2005, p. 9.

¹¹ Nicholas Wade and Choe Sang-Hun, "Researcher Faked Evidence of Human Cloning, Koreans Report," *The New York Times*, Jan. 10, 2006, p. A1.

¹² Dennis Normile, Gretchen Vogel, and Constance Holden, "Cloning Researcher Says Work is Flawed but Claims Results Stand," *Science*, Dec. 23, 2005, p. 1886-1887; Carl T. Hall, "UCSF Resumes Human Embryo Stem Cell Work," *The San Francisco Chronicle*, May 6, 2006, p. A.1.

¹³ Emily Singer, "Stem Cells Reborn," *Technology Review*, May/June, 2006, p. 58-65.

¹⁴ Gareth Cook, "Harvard Team Wants OK to Clone; Human-Cell Work Would Be First in Nation," *Boston Globe*, Oct. 13, 2004, p. A1.

¹⁵ Gareth Cook, "Harvard Provost OKs Procedure," *Boston Globe*, Mar. 20, 2005, p. A29.

for the medical expenses of women who donate eggs. In June 2006, after more than 2½ years, the Harvard group announced that they had received final approval in the review process that looked at ethical, legal and intellectual property issues and involved eight different boards and committees at five separate institutions.¹⁶

In May 2006, scientists at the University of California in San Francisco (UCSF) and Advanced Cell Technology (ACT) in Worcester, MA, independently announced that they would resume their efforts to produce cloned human embryos for research purposes.¹⁷ Both UCSF and ACT (see below) had been working separately on such experiments prior to the February 2004 South Koreans' announcement of cloning success, but subsequently suspended their work; in the case of ACT due to lack of funding and in the case of UCSF due to lack of success.

Clonaid. On December 27, 2002, a representative of Clonaid announced the birth of the first cloned human, a seven-pound baby girl nicknamed Eve. The baby was born on December 26, 2002, at an undisclosed location outside the United States. Although the company offered no proof of its claim, Dr. Brigitte Boisselier, Managing Director of Clonaid, stated that genetic tests would show that the baby is the clone of the 31-year-old American woman who is the birth mother. To date the test results have not been released; the company claims that the parents fear the test results could lead to legal actions and loss of custody of the child.¹⁸ The Clonaid website indicates that "13 cloned babies are now alive," and that "each month, between 10 and 15 implantations will be performed" in the Clonaid laboratory.¹⁹ Clonaid was founded in 1997 by the leader of the Raelians, an international sect of 55,000 people in 84 countries, which claims that life on Earth was created via genetic engineering by a human extraterrestrial race.²⁰

The Food and Drug Administration (FDA) is investigating the company's actions; the agency would consider any human cloning activity to be illegal if performed in the United States.²¹ In April 2001 FDA investigated a Clonaid laboratory in Nitro, WV; the laboratory closed shortly thereafter.²²

Advanced Cell Technology. On November 25, 2001, Advanced Cell Technology (ACT) of Massachusetts announced that it had created the world's first

¹⁶ Sylvia Pagan Westphal, "Harvard Joins New U.S. Push in Stem Cells," *The Wall Street Journal*, Jun. 7, 2006, p. B1.

¹⁷ Ibid.

¹⁸ K. Chang, "Scientist in Clone Tests Says Hoax Is Possible," *New York Times*, Jan. 7, 2003, p. A12.

¹⁹ [<http://www.clonaid.com/news.php>]

²⁰ For further information, see [<http://www.clonaid.com>] and [<http://www.rael.org>].

²¹ L. Greenhouse, "FDA Exploring Human Cloning Claim," *New York Times*, Dec. 30, 2002, p. A10.

²² G. Kolata and K. Chang, "For Clonaid, a Trail of Unproven Claims," *New York Times*, Jan. 1, 2003, p. A13.

human embryos produced via cloning.²³ ACT used two techniques, SCNT and parthenogenesis, to produce human embryos. ACT researchers obtained eggs from seven women, ages 24 to 32, who were paid \$3,000 to \$5,000. In the SCNT approach, scientists removed the nucleus from 19 eggs and replaced it with a nucleus from another adult cell. The nucleus of a skin cell was used for 11 eggs, and for the remaining eight eggs, cumulus cells were used. Eggs that received a skin cell nucleus did not divide; seven of the eggs with the cumulus cell nucleus began to divide but division stopped at the four-to-six-cell stage. In parthenogenesis, an egg cell is treated with chemicals causing it to divide without being fertilized by a sperm. ACT exposed 22 human eggs to the chemicals. After five days, six eggs had matured into a larger mass of cells before division stopped. None of the embryos developed by ACT divided sufficiently to produce stem cells. ACT suspended its work in 2004.

The goal of ACT's work was to produce human embryonic stem cells and develop new therapies for diseases such as diabetes and Parkinson's disease.²⁴ Scientists believe that stem cells transplanted into a patient could treat disease or injury by replacing damaged tissue. If the cell nucleus used in SCNT is from the patient, the stem cells would be genetically identical to the patient, recognized by the patient's immune system, and would avoid any tissue rejection problems that could occur in other stem cell therapeutic approaches. Because of this, many scientists believe the SCNT technique may provide the best hope of eventually treating patients using stem cells for tissue transplantation.

Others with Human Cloning Intentions. Within a year of the Dolly announcement, concerns over human cloning were heightened when Dr. Richard Seed, a Chicago scientist, announced on January 7, 1998, his intention to clone a human being. In response, bills were introduced in the 105th Congress that would have banned human cloning indefinitely or imposed a moratorium. The legislation was opposed by a number of medical organizations, the biotechnology industry and many scientists and was not enacted.

Others who have expressed an interest in reproductive cloning include Dr. Panos Zavos, of the University of Kentucky, and Dr. Severino Antinori, director of a fertility clinic in Rome. At one time, Dr. Zavos and Dr. Antinori were working together to help infertile couples have children via cloning. In April 2002, there were unconfirmed reports in the media that Dr. Antinori had implanted cloned human embryos in women. Dr. Antinori claimed there were three such pregnancies of six-to nine-weeks' duration, two in Russia and one in an Islamic state. His claim was disputed by his former partner Dr. Zavos. In January 2004 Dr. Zavos announced that he had implanted a cloned embryo into a woman's uterus; two weeks later he stated that the pregnancy had failed.²⁵

²³ J. B. Cibelli, et al., "Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development," *Journal of Regenerative Medicine*, vol. 2, Nov. 26, 2001, pp. 25-31.

²⁴ For more information about stem cells, see CRS Report RL31015, *Stem Cell Research*, by Judith A. Johnson and Erin Williams.

²⁵ David Derbyshire and Oliver Poole, "I Am Doing God's Work, Insists Maverick Fertility Expert Who Wants to Clone Babies," *Daily Telegraph*, Feb. 14, 2004, p. 4.

Federal Policy Involving Human Embryo Research

At the present time, no U.S. laws or regulations would prohibit all cloning research. However, federal funding of *any* type of research involving human embryos, starting with *in vitro* fertilization (IVF) then later cloning and the creation of stem cell lines from embryos, had been blocked by various policy decisions dating back 25 years.

Ethics Advisory Board. Following the birth of the first IVF baby, Louise Brown, in July 1978, the federal Ethics Advisory Board (EAB) was tasked with considering the scientific, ethical, legal, and social issues surrounding human IVF.²⁶ The EAB released its report on May 4, 1979, which found that IVF research was acceptable from an ethical standpoint and could be supported with federal funds. The EAB's recommendations were never adopted by HHS, the EAB was dissolved in 1980, and no other EAB was ever chartered. Because federal regulations that govern human subject research (45 C.F.R. Part 46) stipulated that, at the time, federally supported research involving human IVF must be reviewed by an EAB, a so-called "de facto moratorium" on human IVF research resulted. Other types of embryo research ensuing from the development and use of IVF, such as cloning and stem cells, were therefore also blocked. The de facto moratorium was lifted with the enactment of the National Institutes of Health (NIH) Revitalization Act of 1993 (P.L. 103-43, Section 121(c)) which nullified the regulatory provision (45 C.F.R. § 46.204(d)) requiring EAB review of IVF proposals.

NIH Human Embryo Research Panel. In response, the NIH established the Human Embryo Research Panel to assess the moral and ethical issues raised by this research and to develop recommendations for NIH review and conduct of human embryo research. The NIH Panel released a report providing guidelines and recommendations on human embryo research in September 1994. The panel identified areas of human embryo research it considered to be unacceptable, or to warrant additional review. It determined that certain types of cloning²⁷ without transfer to the uterus warranted additional review before the Panel could recommend whether the research should be federally funded. However, the Panel concluded that federal funding for such cloning techniques followed by transfer to the uterus should be unacceptable into the foreseeable future. The NIH Panel recommended that some areas of human embryo research should be considered for federal funding, including SCNT, stem cells and, under certain limited conditions, *embryos created solely for*

²⁶ The EAB was created in 1978 by the Department of Health Education and Welfare (HEW), the forerunner of the Department of Health and Human Services (HHS). The EAB was formed at the recommendation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission operated from 1974 to 1978 and issued 10 reports, many of which formed the basis of federal regulations for research involving human subjects (45 C.F.R. Part 46).

²⁷ These were **blastomere separation**, where a two- to eight-cell embryo is treated causing the cells (blastomeres) to separate; and, **blastocyst division**, in which an embryo at the more advanced blastocyst stage is split into two.

*the purpose of research.*²⁸ The Panel’s report was unanimously accepted by the NIH Advisory Committee to the Director (ACD) on December 2, 1994.

After the ACD meeting on December 2, 1994, President Clinton directed NIH *not* to allocate resources to support the “*creation of human embryos for research purposes.*” The President’s directive did not apply to research involving so-called “spare” embryos, those that sometimes remain from clinical IVF procedures performed to assist infertile couples to become parents. Nor did it apply to human parthenotes, eggs that begin development through artificial activation, not through fertilization. Following the Clinton December 2, 1994 directive to NIH, the agency proceeded with plans to develop guidelines to support research using spare embryos.

Dickey Amendment. NIH plans to develop guidelines on embryo research were halted on January 26, 1996, with the enactment of P.L. 104-99, which contained a rider that affected FY1996 funding for NIH. The rider prohibited HHS from using appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. This same rider, often referred to as the Dickey Amendment, has been attached to the Labor, HHS and Education Appropriations Acts for FY1997 through FY2006.²⁹ For FY2006, the provision is found in Section 509 of the Labor, HHS and Education and Related Agencies Appropriations Act, 2006 (P.L. 109-149). It states that:

(a) None of the funds made available in this Act may be used for —

(1) the creation of a human embryo or embryos for research purposes;

or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 [the Human Subject Protection regulations] as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes [sperm or egg] or human diploid cells [cells that have two sets of chromosomes, such as somatic cells].

²⁸ National Institutes of Health, *Report of the Human Embryo Research Panel*, Sept. 27, 1994.

²⁹ The rider language has not changed significantly from year to year (however, there was a technical correction in P.L. 109-149). The original rider, introduced by Rep. Jay Dickey, is in Section 128 of P.L. 104-99; it affected NIH funding for FY1996 contained in P.L. 104-91. For subsequent fiscal years, the rider is found in Title V, General Provisions, of the Labor, HHS and Education Appropriations Acts in the following public laws: FY1997, P.L. 104-208; FY1998, P.L. 105-78; FY1999, P.L. 105-277; FY2000, P.L. 106-113; FY2001, P.L. 106-554; FY2002, P.L. 107-116; FY2003, P.L. 108-7; FY2004, P.L. 108-199; and, FY2005, P.L. 108-447.

One month after the Dolly announcement, on March 4, 1997, President Clinton sent a memorandum to the heads of all executive departments and agencies making it “absolutely clear that no federal funds will be used for human cloning.” This action extended the congressional ban beyond HHS to all federally supported research. Clinton also urged the private sector to adopt a voluntary ban on the cloning of human beings. The *NIH Guidelines on Stem Cell Research*, published by the Clinton Administration in August 2000, would not have funded research in which: human stem cells are used for reproductive cloning of a human; human stem cells are *derived* using SCNT; or, human stem cells that were derived using SCNT are *utilized* in a research project.

Actions During the Current Bush Administration. On August 9, 2001, President Bush announced that for the first time federal funds would be used to support research on human embryonic stem cells, but funding would be limited to “existing stem cell lines.” In the speech, President Bush stated that he strongly opposes human cloning. Although not mentioned specifically in the August 9 speech, a fact sheet on the White House website states that federal funds will not be used for “the cloning of human embryos for any purpose.”³⁰ In his speech, President Bush announced his intention to name a President’s council, chaired by Dr. Leon Kass of the University of Chicago, “to consider all of the medical and ethical ramifications of biomedical innovation.” The President’s Council on Bioethics, was established for a period of up to two years by Executive Order 13237 on November 28, 2001. The White House announced the other 17 members of the council on January 16, 2002.

The first topic addressed by the Council was human cloning.³¹ Although all Council members voted in opposition to reproductive cloning, they could not come to an agreement on articulating the precise nature of their objection, whether solely safety concerns or which of the various moral objections were most important. In an informal vote on the issue of therapeutic cloning, about half of the 18 members of the Council voiced their support for the therapeutic use of human cloning. Dr. Kass proposed that the Council’s final report reflect both the arguments supporting cloning for the purpose of medical treatment and those against.

At the June 20, 2002, meeting, nine Council members voted to support cloning for medical research purposes, without a moratorium, provided a regulatory mechanism was established.³² Because one member of the Council had not attended the meetings and was not voting, the vote seemed to be nine to eight in favor of research cloning. However, the draft report sent to Council members on June 28, 2002, indicated that two of the group of nine members had changed their votes in favor of a moratorium. Both made it clear that they have no ethical problem with cloning for biomedical research, but felt that a moratorium would provide time for

³⁰ The White House Fact Sheet on embryonic stem cell research is available at [<http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>].

³¹ Transcripts of the Council meetings and papers developed by staff for discussion during the meetings can be found at [<http://www.bioethics.gov>].

³² S.S. Hall, “President’s Bioethics Council Delivers,” *Science*, vol. 297, July 19, 2002, pp. 322-324.

additional discussion.³³ The changed vote took many Council members by surprise, and some on the Council believe that the moratorium option, as opposed to a ban, was thrown in at the last minute and did not receive adequate discussion. In addition, some on the Council believe that the widely reported final vote of 10 to 7 in favor of a moratorium does not accurately reflect the fact “that the majority of the council has no problem with the ethics of biomedical cloning.”³⁴ The final report, *Human Cloning and Human Dignity: An Ethical Inquiry*, was released on July 11, 2002.

In March 2001, the FDA sent letters to the research community stating that the creation of a human being using cloning is subject to FDA regulation under the Public Health Service Act and the Food, Drug and Cosmetic Act.³⁵ FDA stated that such research could only occur when an investigational new drug application (IND) is in effect. Some legal scholars believe that there is no legal basis for the regulation of cloning by FDA.³⁶ They find little evidence to support FDA’s position that cloned human embryos are “drugs.” However, the biotechnology industry and the American Society for Reproductive Medicine believe FDA has the authority to regulate cloning and legislation is unnecessary because FDA regulation is preferred to any new action by Congress.³⁷

On January 18, 2002, the National Academies released its report, entitled *Scientific and Medical Aspects of Human Reproductive Cloning*.³⁸ The panel recommended that the U.S. ban human reproductive cloning. The panel was concerned for the safety of both the woman and the fetus and judged the procedure to be too dangerous for use in humans at the present time. The ban should be legally enforceable, rather than voluntary, and carry substantial penalties. The ban should be reconsidered in five years, but only if compelling new data on safety and efficacy are presented and a national dialogue on the social and ethical issues suggests that a review is warranted. However, the panel concluded that research using SCNT to produce stem cells should be permitted because of the considerable potential for developing new therapies and advancing biomedical knowledge. This position is in agreement with a previous National Academies’ report entitled *Stem Cells and the Future of Regenerative Medicine*, which was released on September 11, 2001.³⁹

³³ Ibid., p. 324.

³⁴ Ibid., p. 322.

³⁵ The FDA position statement and letters to the research community are available at [<http://www.fda.gov/cber/genetherapy/clone.htm>].

³⁶ R. Weiss, “Legal Barriers to Human Cloning May Not Hold Up,” *Washington Post*, May 23, 2001, p. A1.

³⁷ Ibid.

³⁸ The National Academies are the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council. The report on human cloning is available at [http://www.nap.edu/catalog/10285.html?onpi_topnews_011802].

³⁹ The National Academies’ report on stem cell research is available at [http://www.nap.edu/catalog/10195.html?onpi_topnews_091101].

Because of the current lack of federal regulation, the National Academies established in July 2004 the Committee on Guidelines for Human Embryonic Stem Cell Research to develop voluntary guidelines for deriving, handling and using human embryonic stem cells. The stated position of the National Academies is that there should be a global ban on human reproductive cloning and therefore the guidelines will focus only on therapeutic and research uses of human embryonic stem cells and somatic cell nuclear transfer.

The Committee released its “Guidelines for Human Embryonic Stem Cell Research” on April 26, 2005. The guidelines recommend that institutions conducting human embryonic stem cell research should establish oversight committees, including experts in the relevant areas of science, ethics and law, as well as members of the public, to review all proposed experiments. The guidelines recommend that a national panel should be established to oversee the issue in general on a continuing basis. However, the guidelines state that certain types of research should not be permitted at the present time: (1) culture of any intact embryo, regardless of derivation method, for more than 14 days; (2) the insertion of any embryonic stem cells into a human embryo or the insertion of human embryonic stem cells into a nonhuman primate embryo. In addition, animals in which human embryonic stem cells have been introduced, at any stage of development, should not be allowed to breed. The document also provides guidance on informed consent of donors and states that there should be no financial incentives in the solicitation or donation of embryos, sperm, eggs, or somatic cells for research purposes.

The U.S. Supreme Court has recognized in past cases certain personal rights as being fundamental and protected from government interference.⁴⁰ Some legal scholars believe a ban on human cloning may be struck down by the Supreme Court because it would infringe upon the right to make reproductive decisions which is “protected under the constitutional right to privacy and the constitutional right to liberty.”⁴¹ Other scholars do not believe that noncoital, asexual reproduction, such as cloning, would be considered a fundamental right by the Supreme Court. A ban on human cloning research may raise other constitutional issues: scientists’ right to personal liberty and free speech. In the opinion of some legal scholars, any government limits on the use of cloning in scientific inquiry or human reproduction would have to be “narrowly tailored to further a compelling state interest.”⁴²

State Laws on Cloning

As of April 18, 2006, 15 states have passed laws pertaining to human cloning. Arkansas, California, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, New Jersey, North Dakota, Rhode Island, South Dakota, and Virginia have

⁴⁰ For further discussion of these issues and their relationship to human cloning, see CRS Report RL31422, *Substantive Due Process and a Right to Clone*, by Jon O. Shimabukuro.

⁴¹ L. B. Andrews, “Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning,” *Harvard Journal of Law and Technology*, summer 1998, pp. 643-680.

⁴² *Ibid.*, p. 667.

all enacted measures to prohibit reproductive cloning.⁴³ Arizona and Missouri have passed laws that address the use of public funds for cloning. In addition, Louisiana has enacted legislation prohibiting reproductive cloning but the law expired in July 2003. Six of the states also prohibit cloning for research or therapeutic purposes (Arkansas, Indiana, Iowa, Michigan, North Dakota, South Dakota). The Virginia law may also prohibit therapeutic cloning, “but it may be unclear because the law does not define the term ‘human being’ which is used in the definition of human cloning.”⁴⁴ The California and New Jersey laws specifically permit cloning for research purposes. The Rhode Island law is silent on therapeutic cloning and cloning for research purposes, and has a sunset date of July 7, 2010.

Congressional Action

The 109th Congress addressed the issue of cloning and embryo research in the Labor, HHS and Education Appropriations Act of 2006 (P.L. 109-149) by again including the Dickey Amendment, which has banned, since FY1996, almost all publically funded human embryo research. In addition, the Science, Justice and Commerce Appropriations Act, 2006 (P.L. 109-108) bars the Patent and Trademark Office from spending money “to issue patents on claims directed to or encompassing a human organism.” This restriction, which was first included in the Consolidated Appropriations Act, 2004 (P.L. 108-199), and in the Consolidated Appropriations Act, 2005 (P.L. 108-447), could potentially deter human embryo research and stem cell research because researchers might not be able to claim ownership of their work.

H.R. 810 (Castle), the Stem Cell Research Enhancement Act, passed the House on May 24, 2005, on a vote of 238-194. It would amend the Public Health Service Act and direct the Secretary of HHS to conduct and support research that utilizes human embryonic stem cells regardless of the date on which the stem cells were derived from a human embryo. Stem cell lines derived after enactment must meet ethical guidelines established by the NIH. Only embryos that were originally created for fertility treatment purposes and in excess of clinical need are eligible for stem cell derivation. Only embryos that the individuals seeking fertility treatments have determined will not be implanted in a woman and will be discarded are eligible for stem cell derivation. Written consent is required for embryo donation. The Secretary in consultation with the Director of NIH shall promulgate guidelines 60 days after enactment. No federal funds shall be used to conduct research on unapproved stem cell lines. The Secretary shall annually report to Congress about stem cell research. A companion bill, S. 471 (Specter), was introduced on February 28, 2005.

On June 29, 2006, Senate Majority Leader Bill Frist announced an agreement on scheduling a vote in the Senate on stem cell research legislation, more than a year after the House passed H.R. 810. Under the agreement, amendments were not allowed on a package of three bills; each needed 60 votes to pass: H.R. 810, S. 2754 (Santorum) the Alternative Pluripotent Stem Cell Therapies Enhancement Act, and S. 3504 (Santorum) the Fetus Farming Prohibition Act. S. 3504 does not address the

⁴³ National Conference of State Legislatures, State Human Cloning Laws, July 17, 2006, at [<http://www.ncsl.org/programs/health/genetics/rt-shcl.htm>].

⁴⁴ Ibid.

issue of stem cell research but rather the use of tissue from a later stage embryo or fetus.

The second bill in the agreement, S. 2754, was introduced on May 5, 2006. It would amend the Public Health Service Act adding a new Section 409J “Alternative Human Pluripotent Stem Cell Research.” The bill would require the Secretary of HHS to develop techniques for the isolation, derivation, production, or testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of treatments for diseases and other adverse health conditions, but are not derived from a human embryo. Within 90 days of enactment, the Secretary would be required to: (1) provide guidance concerning the next steps required for additional research; (2) prioritize research with the greatest potential for near-term clinical benefit; and (3) take into account techniques outlined by the President’s Council on Bioethics and any other appropriate techniques and research. The Secretary would be required to prepare and submit to the appropriate committees of Congress an annual report describing the activities and research conducted. The bill authorizes such sums as may be necessary for FY2007 through FY2009. A companion bill, H.R. 5526 (Bartlett), was introduced on June 6, 2006.

The third bill, S. 3504, was introduced on June 13, 2006. It would amend the Public Health Service Act to prohibit the solicitation or acceptance of human fetal tissue obtained from a human pregnancy that was deliberately initiated to provide such tissue, or tissue obtained from a human embryo (or fetus) that was implanted in the uterus of a nonhuman animal. The bill was referred to the Senate Health, Education, Labor and Pensions Committee. A companion bill, H.R. 5719 (Weldon), was introduced on June 29, 2006, and referred to the House Energy and Commerce Committee.

On July 18, 2006, the Senate passed H.R. 810 (63 to 37), S. 2754 (100-0) and S. 3504 (100-0). On the same day, the House passed S. 3504 (100-0) but failed to pass S. 2754 with the required 2/3 vote (273-154). On July 19, 2006, President Bush signed S. 3504 and vetoed H.R. 810, the first veto of his six years in office. An attempt in the House on July 19 to override the veto of H.R. 810 did not receive the required 2/3 vote (235-193).

H.R. 1357 (Dave Weldon), the Human Cloning Prohibition Act of 2005, was introduced on March 17, 2005. H.R. 1357 amends Title 18 of the United States Code and would ban the process of human cloning as well as the importation of any product derived from an embryo created via cloning. Under this measure, cloning could not be used for reproductive purposes or for research on therapeutic purposes, which would have implications for stem cell research. H.R. 1357 includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than \$1 million. H.R. 1357 is essentially identical to the measure which passed the House in the 107th Congress (H.R. 2505) and the 108th Congress (H.R. 534). H.R. 1357 was referred to the House Committee on the Judiciary.

A companion bill, S. 658 (Brownback), was introduced on March 17, 2005. It is similar to H.R. 1357, except that (1) it does not contain the ban on importation of products derived from therapeutic cloning; and (2) it amends Title 4 of the Public

Health Service Act (42 U.S.C. §§ 289 et seq.) instead of Title 18 of the United States Code.⁴⁵ S. 658 includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than \$1 million. It requires GAO to conduct a study to assess the need (if any) for any changes of the prohibition on cloning in light of new developments in medical technology, the need for SCNT to produce medical advances, current public attitudes and prevailing ethical views on the use of SCNT and potential legal implications of research in SCNT. The study is to be completed within four years of enactment. S. 658 has been referred to the Senate Health, Education, Labor, and Pensions Committee.

S. 876 (Hatch), the Human Cloning Ban and Stem Cell Research Protection Act of 2005, was introduced on April 21, 2005. A similar bill, H.R. 1822 (Bono), the Human Cloning Ban and Stem Cell Research Protection Act of 2005, was introduced on April 26, 2005. S. 876 amends Title 18 of the United States Code and H.R. 1822 amends the Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.).⁴⁶ Both bills would ban human reproductive cloning but allow cloning for medical research purposes, including stem cell research. S. 876 and H.R. 1822 include a criminal penalty of imprisonment of not more than 10 years; S. 876 has a civil penalty of not less than \$1 million, H.R. 1822 has a civil penalty not to exceed \$10 million.

S. 876 requires the Comptroller General to prepare a series of four reports within one year of enactment. The first report describes the actions taken by the Attorney General to enforce the prohibition on human reproductive cloning, the personnel and resources used to enforce the prohibition, and a list of any violations of the prohibition. A second report describes similar state laws that prohibit human cloning and actions taken by the states' attorney general to enforce the provisions of any similar state law along with a list of violations. A third report describes the coordination of enforcement actions among the federal, state and local governments. A fourth report describes laws adopted by foreign countries related to human cloning. H.R. 1822 requires a similar set of three reports to be prepared by the Secretary of Health and Human Services.

S. 876 and H.R. 1822 would amend the Public Health Service Act by requiring that human SCNT be conducted in accordance with the ethical requirements (such as informed consent, examination by an Institutional Review Board, and protections for safety and privacy) contained in subpart A of 45 C.F.R. Part 46,⁴⁷ or Parts 50 and 56 of 21 C.F.R.⁴⁸ S. 876 and H.R. 1822 have a prohibition on conducting SCNT on fertilized human eggs (oocytes), and both state that "unfertilized blastocysts" shall not be maintained after more than 14 days from its first cell division, aside from

⁴⁵ By seeking to amend Title 18 of the U.S. Code rather than the Public Health Service Act, S. 658 would likely be subject to different committee jurisdiction.

⁴⁶ Because they amend different titles of the U.S. Code, the bills would likely be subject to different committee jurisdiction.

⁴⁷ This provision specifies protections due to human beings who participate in research conducted or supported by HHS and many other departments.

⁴⁸ This provision specifies protections due to human beings who participate in research involved in testing a drug or medical device for FDA approval.

storage at temperatures less than zero degrees centigrade. S. 876 and H.R. 1822 stipulate that a human egg may not be used in SCNT research unless the egg is donated voluntarily with the informed consent of the woman donating the egg. Both bills also specify that human eggs or unfertilized blastocysts may not be acquired, received or otherwise transferred for valuable consideration if the transfer affects interstate commerce. In addition, SCNT may not be conducted in a laboratory in which human eggs are subject to assisted reproductive technology treatments or procedures, such as in vitro fertilization for the treatment of infertility. Violation of these provisions in S. 876 and H.R. 1822 regarding ethical requirements would result in a civil penalty of not more than \$250,000. S. 876 has been referred to the Senate Judiciary Committee. H.R. 1822 has been referred to the House Energy and Commerce Committee.

Supporters of a ban on human cloning, such as that contained in H.R. 1357, argue that a partial ban on human cloning, like the one contained in S. 876, would be impossible to enforce. Critics of the ban on human cloning argue that SCNT creates a “clump of cells” rather than an embryo, and that the ban would curtail medical research and prevent Americans from receiving life-saving treatments created overseas.

Ethical and Social Issues

The possibility of using cloning technology not just for therapeutic purposes but also for reproducing human beings raises profound moral and ethical questions. As previously mentioned, the Bush Administration and the National Academies have made their positions clear. In July 2002, the President’s Council on Bioethics issued its report, *Human Cloning and Human Dignity*, which contained two opinions and sets of recommendations: one of the 10-7 majority, and one of the minority.⁴⁹ The majority and minority both opposed reproductive cloning. It was on the topic of therapeutic cloning, which the majority opposed and the minority favored, that the Council was split.

⁴⁹ At the June 20, 2002, meeting, 9 of 17 Council members voted to support cloning for medical research purposes, without a moratorium, provided a regulatory mechanism was established. Because one member of the Council had not attended the meetings and was not voting, the vote seemed to be nine to eight in favor of research cloning. However, draft versions of the Council report sent to Council members on June 28, 2002, indicated that two of the group of nine members had changed their votes in favor of a moratorium. Both made it clear that they have no ethical problem with cloning for biomedical research, but felt that a moratorium would provide time for additional discussion. The changed vote took many Council members by surprise, and some on the Council believe that the moratorium option, as opposed to a ban, was thrown in at the last minute and did not receive adequate discussion. In addition, some on the Council believe that the widely reported final vote of 10 to 7 in favor of a moratorium does not accurately reflect the fact “that the majority of the council has no problem with the ethics of biomedical cloning.” (Transcripts of the Council meetings and papers developed by staff for discussion during Council meetings can be found at [<http://www.bioethics.gov>]; S.S. Hall, “President’s Bioethics Council Delivers,” *Science*, vol. 297, July 19, 2002, pp. 322-324.) “Wise Words from Across the Pond?” *BioNews*, no. 252, Mar. 29, 2004.

A predecessor to the President's Council, the National Bioethics Advisory Commission (NBAC), recommended, in *Cloning Human Beings*,⁵⁰ the continuation of a moratorium on federal funding for reproductive purposes with a call for voluntary compliance from the private sector. It further recommended the enactment of legislation with a three- to five-year sunset clause banning cloning for reproductive purposes. However, it made clear that all measures taken should "be carefully written so as not to interfere with other important areas of scientific research."⁵¹

Various other organizations, individuals, and councils have issued opinions and reports on cloning as well. Some, such as The United States Conference of Catholic Bishops (USCCB)⁵² oppose human cloning for any purpose: "The cloning procedure is so dehumanizing that some scientists want to treat the resulting human beings as subhuman, creating them solely so they can destroy them for their cells and tissues."⁵³ Others, such as a group of forty Nobel Laureates,⁵⁴ former First Lady Nancy Reagan,⁵⁵ and former President Gerald Ford,⁵⁶ would allow regulated cloning for therapeutic purposes, but disallow it for reproductive ones. Still others, such as such as Dr. Severino Antinori, and Clonaid,⁵⁷ favor cloning for reproductive purposes, and even claim to have created human clones via SCNT.⁵⁸

The human cloning debate centers around number of different ethical and pragmatic issues. Exploration of these issues reveals variation in ethical and moral

⁵⁰ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997.

⁵¹ *Ibid.*, p. iv.

⁵² The United States Conference of Catholic Bishops is "is an assembly of the hierarchy of the United States and the U.S. Virgin Islands who jointly exercise certain pastoral functions on behalf of the Christian faithful of the United States," at [<http://www.nccbuscc.org/whoweare.htm>].

⁵³ Bishop Gregory, President of the United States Conference of Catholic Bishops, quoted in "Bishops' President Says Cloning Turns Human Reproduction into a Manufacturing Process, *United States Conference of Catholic Bishops Communications*, Nov. 27, 2001, at [<http://www.usccb.org/comm/archives/2001/01-205.shtml>].

⁵⁴ The American Society for Cell Biology statement by the 40 Nobel Laureates is available at [<http://www.ascb.org/publicpolicy/Nobelletter.html>].

⁵⁵ Complete text of a letter from Mrs. Reagan to Senator Orrin Hatch specifying her position on cloning can be found at [http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=674].

⁵⁶ L. Hafner, "Revised Feinstein/Kennedy Cloning Bill Has Criminal and Civil Penalties, Requires Research Review," *Washington Fax*, May 2, 2002.

⁵⁷ "CLONAIID™, the first human cloning company in the world, was founded in Feb. 1997, by RAËL and a group of investors who created the Valiant Venture Ltd Corporation based in the Bahamas." The organization was founded by the leader of the Raelian Movement, "the world's largest UFO-related organization." "A Historical Background," *Clonaid*, at [<http://www.clonaid.com/content.php?content>], accessed July 1, 2004.

⁵⁸ See, for example, "Alive and Well," *Clonaid*, at [<http://www.clonaid.com/news.php>], visited July 1, 2004; Abu Dhabi, "Human Cloning Project Claims Progress," *Gulf News Online Edition*, Apr. 3, 2002, at [<http://www.gulf-news.com/Articles/news.asp?ArticleID=46275>].

as well as factual beliefs. The following discussion breaks down the arguments surrounding human cloning according to these issues, demonstrating both the complexity of the issues and the points of resonance among the groups.

Issues Involved in Cloning for Reproductive Purposes. As Clonaid advertised and the President’s Council acknowledged, supporters of reproductive cloning favor it because it might “allow infertile couples to have genetically-related children,”⁵⁹ enable families to avoid genetic disease in their genetically-related children, facilitate the replication of specific persons (such as lost loved ones), or to create ideal transplant donors.⁶⁰ Likewise, the NBAC recognized that some of the principles that underlie these purposes are a “presumption in favor of individual liberty,” that “human reproduction [is] particularly personal and should remain free of constraint, ... [and] as a society, we ought not limit the freedom of scientific inquiry.”⁶¹ However, for a number of other reasons, the idea of cloning for reproductive purposes is presently rejected by most groups and organizations, including the President’s Council and NBAC. Of the groups and individuals listed in the Ethical and Social Issues section, only Clonaid and Dr. Antinori favor reproductive cloning at this time. Despite the apparent uniformity of views rejecting reproductive cloning, there is a great deal of variation in the lines of reasoning underlying such objections.

Procreation Without Conjugal Union. According to the USCCB, *Donum Vitae*⁶² instructs that “attempts or hypotheses for obtaining a human being without any connection with sexuality through ‘twin fission,’ cloning or parthenogenesis are to be considered contrary to the moral law, since they are in opposition to the dignity both of human procreation and of the conjugal union.”⁶³ This objection to reproductive cloning, that procreation should be limited to conjugal unions, is not supported by most groups. If accepted, it would lead to a rejection of other forms of assisted reproduction, such as in vitro fertilization (IVF). Of the groups and individuals listed above, only UCCSB cites the need for a conjugal union as a persuasive argument against reproductive cloning.

Safety. The most agreed upon objection to human reproductive cloning is one of safety. The President’s Council on Bioethics concluded that, “[g]iven the high

⁵⁹ President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxvii. (Hereafter cited as President’s Council, *Human Cloning*.)

⁶⁰ See, for example, President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxvii; “Frequently Asked Questions,” *Clonaid*, at [<http://www.clonaid.com/content.php?content.6>], accessed July 9, 2004.

⁶¹ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 72.

⁶² *Donum Vitae*, (“The Gift of Life”), which addresses the Catholic view of morality of many modern fertility procedures, was issued in 1987 by the Sacred Congregation for the Doctrine of the Faith at [<http://www.nccbuscc.org/prolife/tdocs/donumvitae.htm>], accessed July 9, 2004.

⁶³ John Haas, “Begotten Not Made: A Catholic View of Reproductive Technology,” *United States Conference of Catholic Bishops, Pro Life Activities*, June 2003, at [<http://www.usccb.org/prolife/programs/rfp/98rlphaa.htm>], accessed July 9, 2004.

rates of morbidity and mortality in the cloning of other mammals, we believe that cloning-to-produce-children would be extremely unsafe, and that attempts to produce a cloned child would be highly unethical.”⁶⁴ The National Bioethics Advisory Commission reached a consensus in its objection to reproductive cloning “because current scientific information indicate[d] that this technique [was] not safe in humans....”⁶⁵ The National Academies agrees with this line of reasoning, given that animal experimentation has demonstrated that “only a small percentage of attempts are successful,” “many of the clones die during gestation,” and “newborn clones are often abnormal, or die.”⁶⁶ While these objections about safety are widely held, they may be temporary in nature. As research advances, it may become less risky, and thus some may find it less objectionable to attempt reproductive human cloning.

Unlike concerns about safety, other types of objections, while not so widely held, may be more lasting because they are not likely to be alleviated by scientific progress. These tend to be philosophical in nature. These concerns, listed in the following paragraphs, have been acknowledged by the President’s Council, NBAC, UCSSB, and the National Academies. According to the President’s Council, “[d]ifferent Council members give varying moral weight to [the following] different concerns.”⁶⁷ Only the UCSSB found the concerns persuasive in total.

Identity. Some objections to reproductive cloning are based upon fears that cloned children will have difficulty with their identities “because each will be genetically virtually identical to a human being who has already lived and because the expectations for their lives may be shadowed by constant comparisons to the life of the ‘original.’”⁶⁸ These concerns are dismissed by others, who point out that this argument rests largely on “the crudest genetic determinism.”⁶⁹ They cite both the effect that environment plays on individual development, and the lack of difficulty with identity experienced by naturally occurring identical twins.⁷⁰

Commodification. Other philosophical objections have to do with a fear that cloned children “might come to be considered more like products of a designed

⁶⁴ President’s Council, *Human Cloning*, p. xxiii.

⁶⁵ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. iii.

⁶⁶ *Scientific and Medical Aspects of Human Reproductive Cloning* (Washington: National Academies Press, 2002), p. 93. The report on human cloning is available at [http://www.nap.edu/catalog/10285.html?onpi_topnews_011802].

⁶⁷ The number of Council members who give moral weight to each argument, and the amount of weight they give to each issue is not specified. President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxviii.

⁶⁸ President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxviii.

⁶⁹ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 65. Note: *genetic determinism* is the idea that a person’s identity and development are primarily or entirely the result of his or her genetic makeup. Genetic determinism is generally viewed as a flawed concept because of its failure to acknowledge the impact of environmental factors and the opportunity for individual choice.

⁷⁰ President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. 103.

manufacturing process than ‘gifts’ whom their parents are prepared to accept as they are. Such an attitude toward children could also contribute to increased commercialization and industrialization of human procreation.”⁷¹ This, in turn, may fuel a new eugenics in which parents select not only whether to have a child, but which child to have.⁷² Others point out that these types of concerns were raised about most forms of assisted reproduction (such as in vitro fertilization and preimplantation genetic diagnosis), which have not led to objectification. In addition, if being born is considered to be a benefit to the one born, “to the extent that the technology is used to benefit the child ... no objectification of the child takes place.”⁷³

Familial Relationships. A complicated lineage has also been introduced as an objection to reproductive cloning: “By confounding and transgressing the natural boundaries between generations, cloning could strain the social ties between them. Fathers could become “twin brothers” to their “sons”; mothers could give birth to their genetic twins; and grandparents would also be the “genetic parents” of their grandchildren. Genetic relation to only one parent might produce special difficulties for family life.”⁷⁴ Others point out that children “born through assisted reproductive technologies may also have complicated relationships to genetic, gestational, and rearing parents ... [yet] there is no evidence that confusion over family roles has harmed children born through assisted reproductive technologies, although the subject has not been carefully studied.”⁷⁵

Societal View of Children. Concerns have been voiced about the effects of cloning on society: “Cloning-to-produce-children would affect not only the direct participants but also the entire society that allows or supports this activity. Even if practiced on a small scale, it could affect the way society looks at children and set a precedent for future nontherapeutic interventions into the human genetic endowment or novel forms of control by one generation over the next.”⁷⁶ This objection is rejected by others, who argue that “people can, and do, adapt in socially redeeming ways to new technologies ... [A] child born through somatic cell nuclear transfer could be loved and accepted like any other child....”⁷⁷

Issues Involved in Cloning for Therapeutic Purposes.⁷⁸ Cloning for therapeutic purposes is more broadly supported than reproductive cloning, and the issues involved are somewhat different. The safety concerns of reproductive cloning

⁷¹ Ibid., pp. xxviii-xxix.

⁷² Ibid., p. xxix.

⁷³ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 70.

⁷⁴ President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxix.

⁷⁵ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 66.

⁷⁶ President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxix.

⁷⁷ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 67.

⁷⁸ For purposes of this section, the term “therapeutic purposes” is meant to include the use of cloning technology for both the research underlying treatments and the treatments themselves.

do not apply in therapeutic cloning, placing much of the scientific community, such as the National Academies, in favor of it. In addition, the NBAC, a minority of the President's Council, the group of Nobel Laureates, Nancy Reagan, and Gerald Ford also generally support cloning for therapeutic purposes. Opponents include a majority of the President's Council, and the USCCB.

Relief of Human Suffering and Moral Status of Cloned Embryos.

The central debate over therapeutic cloning rests on the relative weight ascribed to potential research benefits, and that ascribed to cloned embryos themselves. All sides generally agree that research involving cloning may generate biomedical advancements that relieve human suffering. As described the President's Council, the research "may offer uniquely useful ways of investigating and possibly treating many chronic debilitating diseases and disabilities, providing relief to millions."⁷⁹ Yet a majority of Council members were dissuaded from the research, arguing that "[i]f we permit this research to proceed, we will effectively be endorsing the complete transformation of nascent human life into nothing more than a resource tool."⁸⁰ Similar arguments are made by the USCCB.

The Council's minority offered an opposing viewpoint: "We believe there are sound moral reasons for not regarding the embryo, in its earliest stages as the moral equivalent of a human person" but rather as having a "developing and intermediate moral worth that commands our special respect."⁸¹ The minority based its opinion on the fact that, at the blastocyst stage (the one useful for stem cell research, for example), the cells are still undifferentiated and could still be split and develop into two separate twinned embryos, "suggesting that the earliest stage embryo is *not yet* an individual."⁸² Furthermore, they note that the possibility for the development of a human child from a cloned embryo would require its transference to a uterus, as is currently the case with IVF.⁸³ IVF often results in the creation of embryos that remain unimplanted, and is permitted in the United States. For all of the above reasons, the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates support therapeutic cloning.

In July 2004, Dr. Paul McHugh, a member of the President's Council who objects to the destruction of human embryos and who had voted with the Council majority for a moratorium on cloning-for-biomedical research, argued in a medical journal article that SCNT "resembles a tissue culture," and that the products of SCNT should be available for research once regulations are in place to ensure that SCNT is conducted ethically.⁸⁴ At the December 2004 Council meeting, Dr. William

⁷⁹ President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, pp. xxxi, xxxiii.

⁸⁰ *Ibid.*, p. xxxiii.

⁸¹ *Ibid.*, p. xxxi

⁸² *Ibid.*, p. 136.

⁸³ *Ibid.*

⁸⁴ Paul McHugh, "Zygote and 'Clonote' — The Ethical Use of Embryonic Stem Cells," *New* (continued...)

Hurlbut, another Council member who objects to the destruction of human embryos and voted for the moratorium, made a proposal to explore the possibility of using SCNT in combination with techniques to ensure that the group of cells created cannot give rise to human life but can generate embryonic stem cells. Dr. Hurlbut explained, “using the technique of nuclear transfer, it may be possible to produce embryonic stem cells within a limited cellular system that is biologically and morally akin to a complex tissue culture and thereby bypass moral concerns about the creation and disruption of human embryos.”⁸⁵ Some have criticized Dr. Hurlbut’s proposal to create something that is not an embryo, yet generates embryonic stem cells, as one focused on a “semantic issue, not a scientific one.”⁸⁶ Others have lauded Dr. Hurlbut’s proposal as a potential scientific solution to a moral problem. Included among them is Dr. Leon Kass, the Chair of the Council and a well-known opponent of embryo destruction, who said the proposal raises the possibility that, “the partisans of scientific progress and the defenders of nascent human life can go forward in partnership without anyone having to violate things they hold dear.”⁸⁷

Deliberate Creation for Use/Destruction. A second set of considerations underlying the debate have to do with a moral aversion to the prospect of creating life in order to destroy it. As a majority of the President’s Council pointed out, cloning for therapeutic purposes requires “the creation of human life expressly and exclusively for the purpose of its use in research, research that necessarily involves its destruction, ... transform[ing] nascent human life into nothing more than a resource tool.”⁸⁸ The USCCB agrees with this characterization.

The Council minority countered that the “embryos would not be ‘created for destruction,’ but for use in the service of life and medicine.”⁸⁹ Further, the “practice of sacrificing the life of the unborn in order to save the live of the pregnant woman — while not a moral parallel to the case of using cloned embryos for biomedical research — shows that there is some moral precedent for subordinating nascent human life to more developed human life.”⁹⁰ The NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates agree with this characterization.

⁸⁴ (...continued)

England Journal of Medicine, vol. 351, no. 3 (July 15, 2004), p. 210, at [<http://content.nejm.org/cgi/content/full/351/3/209>].

⁸⁵ President’s Council on Bioethics, Presentation of Dr. William Hurlbut in “Transcript of the President’s Council on Bioethics,” Dec. 3, 2004, Washington, D.C., at [<http://www.bioethics.gov/transcripts/dec04/session6.html>].

⁸⁶ Kirsty Horsey, “When Is an Embryo Not an Embryo?” *BioNews*, no. 287, Dec. 6, 2004, at [<http://www.bionews.org/commentary.lasso?storyid=2372>].

⁸⁷ David Brown, “Two Stem Cell Options Presented; Human Embryos Wouldn’t Be Killed,” *Washington Post*, Dec. 4, 2004, A1.

⁸⁸ President’s Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxxiii.

⁸⁹ *Ibid.*, p. xxxi.

⁹⁰ *Ibid.*, pp. 137-138.

Moral Harm or Benefit to Society. The effect of therapeutic cloning upon society has been debated by opponents and proponents alike. The President's Council majority fear negative effects, such as the subjugation of weak members of society, or genetic manipulation of developing life: "As much as we wish to alleviate suffering now and to leave our children in a world where suffering can be more effectively relieved, we also want to leave them in a world ... that honors moral limits, that respects all life whether strong or weak, and that refuses to secure the good of some human beings by sacrificing the lives of others."⁹¹ Approving therapeutic cloning would harm society by "crossing the boundary from sexual to asexual reproduction, thus approving in principle the genetic manipulation and control of nascent human life."⁹² USCCB also shares this point of view.

Counter arguments have been made by those who note that "[h]istorically, scientific inquiry has been protected and even encouraged because of the great societal benefit the public recognizes in maintaining the sanctity of knowledge and the value of intellectual freedom."⁹³ In addition, they note that cloning is replication, rather than transformation: "In an important sense, cloning is not the most radical thing on the horizon. Much more significant ... would be the ability to actually alter or manipulate the genome of offspring, ... which could then lead to a child being born with characteristics other than it would have had...."⁹⁴ The Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates share this perspective.

Going Too Far or Drawing Appropriate Limitations. Some, such as the majority of the President's Council and USCCB, believe that policies allowing therapeutic cloning would create a slippery slope, "opening the door to other moral hazards, such as cloning-to-produce-children or research on later-stage embryos and fetuses."⁹⁵ Others, such as the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates, believe that it is possible to circumscribe acceptable practices with good policy. "Both the federal government and the states already regulate the researchers' methods in order to protect the rights of research subjects and community safety."⁹⁶ Government might regulate "the secure handling of embryos, licensing and prior review of research projects, the protection of egg donors, and the provision of equal access to benefits."⁹⁷

Egg Procurement. The topic of egg procurement came to the public's attention in November 2005 with allegations that some human eggs used in South Korean scientist Dr. Hwang's laboratory had been obtained under coercive

⁹¹ Ibid., p. xxxiv.

⁹² Ibid., p. xxxiv.

⁹³ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 75.

⁹⁴ J.A. Robertson, "A Ban on Human Cloning Research Is Unjustified," *Testimony before the National Bioethics Advisory Commission* (Mar. 14, 1997), in National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 68.

⁹⁵ President's Council, *Human Cloning*, p. xxxiv.

⁹⁶ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 75.

⁹⁷ President's Council, *Human Cloning*, p. xxxviii.

conditions. The alleged situation in Dr. Hwang's laboratory raises the issue of coercion both because subordinate women in the laboratory allegedly donated eggs, and because some women were allegedly paid for their eggs. A 2002 study conducted by a University of Pennsylvania student raised the issue of insufficient information, finding that a number programs seeking donor eggs for reproductive purposes were not up front about the risks involved in egg retrieval. The wide consensus regarding the need for informed consent necessarily implies similar consensus on the need for an information-rich, coercion-free method of obtaining eggs; however, there is some disagreement on the specifics of whether payment for eggs necessarily constitutes coercion.

The prospect of paying women for their eggs, which has been debated in the context of seeking donor eggs both for reproductive purposes (for example, to enable women who do not produce their own eggs to become pregnant), and for research purposes, is not unheard of in the United States. According to a 2000 study by the American Society of Reproductive Medicine (ASRM), some IVF programs reportedly offered as much as \$5,000 for one egg retrieval cycle, though \$2,500 appeared to be a more common amount. Offers of much higher amounts (\$50,000-\$100,000) have been reported elsewhere. Dr. Huang's laboratory reportedly made payments of \$1,400 to each woman who donated eggs. Payments are not illegal in the United States, nor were they illegal in South Korea at the time Dr. Huang's laboratory allegedly made them. The questions are, is payment for egg donation ever acceptable, and if so, what amount is appropriate?

Several arguments have been put forth in favor of payment for egg donation, many focused on donation for reproductive purposes. First, some have argued that payment creates incentives to increase the number of egg donors, thus facilitating research and benefitting infertile couples. Second, some reason that payment for eggs gives women parity with sperm donors, who may be compensated for donating gametes at a lower rate, given that they require a much less involved procedure. Third, some allege that fairness dictates that women who donate eggs ought to be able to benefit from their action. Fourth, some claim that pressures created by financial incentives may be no greater than those experienced by women asked to make altruistic egg donations for relatives or friends, and may thus not rise to the level of coercion. These are the types of arguments that led ASRM to recommend in 2000 that sums of up to \$5,000 may be appropriate for typical egg donation, while sums of up to \$10,000 may possibly be justified if there are particular difficulties a woman must endure to make her donation.

Several arguments have also been put forth against payment for egg donation. First, some voiced fears that payment might lead to the exploitation of women, particularly poor women, and the commodification of reproductive tissues. Second, some have argued that payment for eggs for research purposes might undermine public confidence in endeavors such as human ESR. Arguments such as these have prompted both the NAS and the PCBE to recommend that women not be paid for donating their eggs for research purposes. It also led the PCBE to note that in theory, there is the possibility that eggs could be procured from ovaries harvested from cadavers, which might at least alleviate concerns related to coercion.

It is worth noting that a woman may choose to undergo egg retrieval for her own reproductive purposes, which would effectively take the process of egg procurement out of the research arena and avoid the question of payment entirely. (For example, this could be an option for a woman seeking IVF because her fallopian tubes are blocked).

Types of Restrictions. One final set of arguments center around the types of actions that the government may take with respect to therapeutic and/or reproductive cloning. These include permitting, regulating, funding, discouraging, and temporarily or permanently banning the practices. As a starting point, NBAC offers: “In the United States, governmental policies that prohibit or regulate human actions require justification because of a general presumption against governmental interference in individual activities.”⁹⁸ As may be expected, the opinions regarding appropriate courses of action are largely linked to points of view about the appropriateness of the various endeavors.

The most permissive approach available, permitting cloning with no restrictions, is not supported by any of the individuals or organizations referenced herein. By contrast, the next most permissive approach, regulating cloning, is supported by the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates as appropriate for therapeutic cloning, so as to enable it to continue in accordance with socially accepted scientific research practices. As summarized by the Council minority, “We believe that this research could provide relief to millions of Americans, and that the government should therefore support it, within sensible limits imposed by regulation.”⁹⁹

A voluntary prohibition, the third most permissive approach, was recommended by NBAC as the appropriate immediate response to reproductive cloning by the private sector. NBAC called for “an immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium.”¹⁰⁰

As a longer term approach, NBAC recommended the fourth most permissive approach, a temporary ban on reproductive cloning. “Federal legislation [should] be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period (three to five years) in order to decide whether the prohibition continues to be needed.”¹⁰¹ Readers may be interested to note that, if enacted in 1997 when NBAC’s report was published, a five-year ban on reproductive cloning would have expired in 2002. The National Academies also recommended a ban on reproductive cloning, and did not call it temporary but did add that it should be reconsidered every five years. On the topic of therapeutic rather than reproductive

⁹⁸ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 78.

⁹⁹ President’s Council, *Human Cloning*, p. xxxviii.

¹⁰⁰ National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 105.

¹⁰¹ *Ibid.*

cloning, a majority of the Council recommended a temporary moratorium as the proper approach, because it would “reaffirm the principle that science can progress while upholding the community’s moral norms, and would therefore reaffirm the community’s moral support for science and biomedical technology.”¹⁰²

The most restrictive approach to cloning, a permanent ban, was proposed by the Council minority and majority, and Nancy Reagan as appropriate for reproductive cloning. “By permanently banning cloning-to-produce children, this policy gives force to the strong ethical verdict against [it], unanimous in the Council ... and widely supported by the American people.”¹⁰³ This approach is also favored by the USCCB not only for reproductive cloning, but also for therapeutic cloning.

One related issue, that of the use of federal funding for therapeutic cloning, has also been discussed. No proposals have been made by any of the groups or individuals listed above for the use of federal funding for reproductive cloning. Opponents of funding therapeutic cloning, such as the Council majority, have expressed concern that use of federal funding for therapeutic cloning would put “the federal government in the novel and unsavory position of mandating the destruction of nascent human life.”¹⁰⁴ Proponents of federal funding for therapeutic cloning, such as the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates, cite as support the advancements that might be powered by the infusion of federal dollars into the research, as well as the ethical protections that would attach with the money.

¹⁰² President’s Council, *Human Cloning*, p. xxxvii.

¹⁰³ President’s Council, *Human Cloning*, p. xxxiv.

¹⁰⁴ President’s Council, *Human Cloning*, p. xxxvi